Editorials represent the opinions
of the authors and THE JOURNAL and not those of
the American Medical Association.

Medicare Quality Improvement
Bad Apples or Bad Systems?

David C. Hsia, JD, MD, MPH

THE QUALITY IMPROVEMENT GROUP AT THE CENTERS for Medicare and Medicaid Services leads the quality improvement organizations (QIOs, formerly the PROs [peer review organizations], PSROs [professional standards review organizations], EMCROs [experimental medical care review organizations], etc),[1] and according to the results of a study by Jencks and colleagues[2] in this issue of THE JOURNAL, their leadership is effective. No other US organization measures quality at the hospital level. The QIO program uses 24 quality indicators that have strong evidence to support them. Jencks et al report that between 1999 and 2001, the proportion of Medicare patients receiving appropriate care improved from 70% to 73% on average, although this rate varied widely across states and by indicator.[2] Their analysis is valid, robust, understandable, and correct. For the 1999-2002 QIO contract cycle, Centers for Medicare & Medicaid Services required all QIOs to improve quality in 5 clinical areas (acute myocardial infarction, heart failure, pneumonia, surgical infection, and outpatient diabetes), not just to passively review charts.[3] The QIO quality indicators address some aspects of suboptimal quality, but others remain.

As summarized in the Institute of Medicine's recent reports on medical errors, a diverse literature describes the imperfect state of health care quality.[4] The Institute of Medicine asserts that medical errors kill more people in the United States each year than motor vehicle crashes.[5] For complex reasons, existing systems of quality assessment, review, and improvement function suboptimally.[6]

A critical issue is whether these errors represent failures of humans or systems. Peer review, malpractice litigation, medical licensing, medical disciplinary actions, insurer audit, governmental investigation, and most other quality assurance systems rely on retrospective review. Examining patient charts assumes that error derives from failure on the part of an incompetent or careless individual. Adverse events therefore identify bad apples for removal.[7] This inspection model ("name, blame, shame") seeks to improve quality by cutting off one tail of the bell-shaped curve of human performance.

See also p 305.

In contrast, Deming's continuous quality improvement (CQI) model assumes that most adverse events represent system failures and that design of work processes should detect and eliminate the human error that inevitably occurs.[8] Industrial quality control statistically analyzes all outcomes for systems improvement opportunities rather than searching for single events that purportedly demonstrate individual error. The CQI model seeks to improve quality by moving the entire bell curve to the left.

Unfortunately, the CQI initiative has not yet attained full acceptance by the general public. The name-blame-shame model produces readily understandable headlines, but it does not methodically eliminate errors to improve statistical outcomes. Yet even if every worker in a health care system could do his or her job perfectly, most events that are considered to be errors would still occur. Although organizations like the Institute for Healthcare Improvement have led the effort to extend the CQI initiative into health care,[9] the recent survey by Blendon et al[10] makes it clear that neither members of the public nor physicians appreciate that poor systems cause most errors.

According to the classic Donabedian model,[11] health care quality is organized as structure, process, or outcome. *Structure* refers largely to the paper qualifications of the practitioner or institution (eg, licensed, board certified, insured, or inspected by the Joint Commission on Accreditation of Healthcare Organizations). *Process* refers to how the practitioner delivers care (eg, drug X was indicated and prescribed). *Outcome* refers to what happened subsequently to the patient (eg, felt better, returned to work, died).

At present, all organizations use process measures for quality review. The QIOs surpass other organizations by using validated measures and in aggregating at the hospital level. To secure hospitals' cooperation, the QIOs do not publish their hospital-level results. Rather, these results guide the QIOs in targeting technical assistance to improve quality.[12]

Levels of aggregation at the regional or state level lack sufficient detail to identify opportunities for quality reengineering within a hospital. The upcoming Agency for Healthcare Research and Quality (AHRQ) national quality

Author Affiliation: Agency for Healthcare Research and Quality, US Department of Health and Human Services, Rockville, Md.
Corresponding Author and Reprints: David Hsia, JD, MD, MPH, Agency for Healthcare Research and Quality, 6010 Executive Blvd, Rockville, MD 20852-3809 (e-mail: dhsia@ahrq.gov).

©2003 American Medical Association. All rights reserved.

reports will measure state and national performance with which hospitals can compare their performance. The National Committee for Quality Assurance report cards give Health Employer Data and Information Set (HEDIS)[13] and Consumer Assessment of Health Plans[14] quality indicators for single health plans.[15] However, low-scoring plans have sometimes terminated their public reporting of National Committee for Quality Assurance (NCQA) results.[16] The NCQA has proposed hospital-level report cards, and the National Quality Forum has drafted standardized performance measures for evaluating hospital quality.[17] The American Hospital Association, the Association of American Medical Colleges, and the Federation of American Hospitals have recently proposed voluntary, public reporting of 10 quality indicators, a subset of the National Quality Forum performance measures.[18] Public reports should stimulate CQI and inform patient choices.[19]

Theoretically, outcomes best assess quality, but they are the most difficult to measure because of varying inputs (eg, severity of illness, multiple comorbidities, patient compliance, local conditions). Using processes linked to the outcomes of interest offers higher efficiency but also lower sensitivity to differences in severity of illness process (variability in outcomes may be caused by patient characteristics rather than differences in quality of medical care).[20] Outcome analyses also require high volumes of detailed data to be representative across systems (including, for example, transaction data from multiple payers). These analyses also require longer periods to complete (eg, 5-year cancer survival), thereby preventing timely improvements. Centers for Medicare & Medicaid Services led the use of output measures from 1988 through 1992,[21,22] but it had to abandon them because of political sensitivities.[23]

Although the quality measures assessed vary, health services research has largely reached a consensus on the superiority of explicit measures (comparison to an objective standard) over implicit measures (unstructured review).[24] Peer reviewers reading the same patient records without guidance have low interrater agreement.[25] Explicit review has also become largely condition specific (eg, use of β-blockers after acute myocardial infarction) rather than generic (eg, all-cause mortality).

The literature discussing quality improvement suggests several opportunities to build on the QIO's results. First, Medicare and other payers currently each impose their own quality assurance programs, pulling the hospital in conflicting directions. In addition to supporting the initiative from the American Hospital Association, the Association of American Medical Colleges, and the Federation of American Hospitals, Medicare could refrain from separate QIO audit of institutions attaining a satisfactory grade and pool transaction data with other payers for quality analysis of hospitals declining to participate.

Second, some medical specialties could improve by following the lead of anesthesiology, which has perhaps progressed the most in error-proofing its systems. Human factors analysis identified high mortality due to operators' using unfamiliar ventilators and inadvertently turning off patients' oxygen.[26] Anesthesiology organizations and manufacturers worked together to design new ventilators with standardized controls and on which the oxygen level cannot be physically reduced below room air. These hardware changes largely eliminated human error from the system.[27,28]

Other medical specialties that also depend heavily on medical equipment, such as radiology, pathology, blood banking, nuclear medicine, cardiology, nephrology, and possibly ophthalmology, should also have opportunity for error reduction through hardware and systems reengineering. Public and private payers could lead a consortium to develop and finance human factors analysis, device standardization, and operator training in these and other hardware-dependent medical specialties.[29]

Work process design within a health care system presents a more difficult challenge. Each department and medical specialty functions independently, with workers exhibiting varying degrees of individualism. For instance, diagnostic tests might get scheduled at conflicting times, laboratory samples may disappear in transit, and pharmacists might misread physicians' abbreviations. Interdisciplinary teams have not proved to be a panacea.[30] Hospital management needs to identify opportunities for errors and then create work systems that prevent them. It must also resolve the tension between the command, control, and centralization needed to change an organization's culture and work processes vs the bottom-up approach characteristic of the CQI model.

Extending CQI to the physician office presents even greater challenges.[31] A sole practitioner generally lacks the resources, incentive, and objectivity to reengineer office systems to eliminate human error. An incremental approach might first extend error prevention systems to health care settings organized around institutions, such as ambulatory surgery centers, nursing homes, and clinical laboratories, with subsequent deployment to the office setting.

Several technologies have demonstrated effectiveness in reducing health care errors including physician order entry systems,[32] pharmaceutical software (drug-drug interactions, drug allergies, dosing),[33] and decision support systems.[34,35] Potential extensions of this technology include reporting laboratory and test results, medication tracking (bar coding of unit doses), patient and staff authentication and location (radio frequency identification tags), and order entry and laboratory results by wireless personal computer or personal digital assistant, as well as making these modules interact usefully. Adoption of these innovations has proceeded slowly.[36] Likewise, the computer-based patient record has disseminated more slowly than anticipated.[37] At present, the military and the Department of Veterans Affairs have the most advanced and successful computer-based patient record systems.[38] However, civilian hospitals

©2003 American Medical Association. All rights reserved.

typically do not exercise the same degree of control over their workers as do federal institutions.

In conclusion, the QIOs constitute the nation's main infrastructure for quality improvement. Although applicable to Medicare beneficiaries, the QIOs must exert a spillover effect on other patients. The article by Jencks and colleagues demonstrates their success at improving quality of care and sustaining those improvements. The Institute of Medicine reports underscore the urgency of building on the success of the QIO program to improve the quality of health care for all patients.

Disclaimer: The views presented in this editorial do not represent the policy of any US governmental agency.

Acknowledgment: AHRQ librarians Deby K. Blum, MLS; Renee A. W. McCullough, MHum, MLS; and Lynette F. Lilly, BA, helped obtain references cited in this editorial.

REFERENCES

1. Sprague L. *Contracting for Quality: Medicare's Quality Improvement Organizations*. Washington, DC: National Health Policy Forum; 2002. Issue Brief No. 774.
2. Jencks SF, Huff ED, Cuerdon T. Change in the quality of care delivered to Medicare beneficiaries, 1998-1999 to 2000-2001. *JAMA*. 2003;289:305-312.
3. Quality Improvement Organizations (QIOs) statement of work. Centers for Medicare & Medicaid Services Web site. Available at: http://www.cms.hhs.gov/qio/2.asp. Accessed December 27, 2002.
4. Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.
5. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000:1.
6. Hsia DC. DHHS Office of Inspector General: an overview. *R I Med J*. 1989;72:47-55.
7. Berwick DM. Continuous quality improvement as an ideal in health care. *N Engl J Med*. 1989;320:53-56.
8. Deming WE. *Out of the Crisis*. Cambridge, Mass: MIT Press; 2000.
9. Institute for Healthcare Improvement Web site. Available at: http://www.ihi.org. Accessed December 23, 2002.
10. Blendon RJ, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med*. 2002;347:1933-1940.
11. Donabedian A. *The Definition of Quality and Approaches to Its Assessment*. Ann Arbor, Mich: Health Administration Press; 1980.
12. Berwick DM. Public performance and the will for change. *JAMA*. 2002;288:1523-1524.
13. Health Plan Employer Data and Information Set. National Committee for Quality Assurance Web site. Available at: http://www.ncqa.org/Programs/HEDIS/. Accessibility verified December 27, 2002.
14. Consumer Assessment of Health Plans. Agency for Healthcare Research and Quality Web site. Available at: http://www.ahcpr.gov/qual/cahpsix.htm. Accessibility verified December 27, 2002.
15. National Committee for Quality Assurance Web site. Washington, DC. Available at: http://www.ncqa.org/. Accessed December 23, 2002.
16. McCormick D, Himmelstein DU, Woolhandler S, Wolfe SM, Bor DH. Relationship between low quality-of-care scores and HMOs' subsequent public disclosure of quality-of-care scores. *JAMA*. 2002;288:1484-1490.
17. National Quality Forum Web site. Washington, DC. Available at: http://www.qualityforum.org/. Accessed December 23, 2002.
18. Hospitals to share quality information [news release]. Washington, DC: American Hospital Association, December 12, 2002. Available at: http://www.hospitalconnect.com/aha/press_room-info/releasedisplay.jsp?dcrpath=AHA/Press_Release/data/PR_021212_Quality&domain=AHA. Accessed December 23, 2002.
19. Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: what do we expect to gain? *JAMA*. 2000;283:1866-1874.
20. Mant J, Hicks N. Detecting differences in quality of care: the sensitivity of measures of process and outcome in treating acute myocardial infarction. *BMJ*. 1995;311:793-796.
21. Hartz AJ, Krakauer H, Kuhn EM, et al. Hospital characteristics and mortality rates. *N Engl J Med*. 1989;321:1720-1725.
22. Krakauer H, Bailey RC, Skellan KJ, et al. Evaluation of the HCFA model for the analysis of mortality following hospitalization. *Health Serv Res*. 1992;27:317-335.
23. Wilensky GR. Contracting for quality: Medicare's quality improvement organizations. Presented at: the National Health Policy Forum; September 27, 2002; Washington, DC.
24. McGlynn EA, Brook RH. Evaluating the quality of care. In: Andersen RM, Rice TH, Kominski GF, eds. *Changing the US Health Care System: Key Issues in Health Services, Policy, and Management*. 2nd ed. San Francisco, Calif: Jossey-Bass; 2001:150-182.
25. Clement DG, Retchin SM, Brown RS, Stegall MH. Access and outcomes of elderly patients enrolled in managed care. *JAMA*. 1994;271:1487-1492.
26. Gawande A. When doctors make mistakes: the real problem isn't how to stop bad doctors from harming, even killing, their patients; it's how to prevent good doctors from doing so. *New Yorker*. 1999;74:40-55.
27. Bates DW, Gawande AA. Error in medicine: what have we learned? *Ann Intern Med*. 2000;132:763-767.
28. Cooper JB, Gaba D. No myth: anesthesia is a model for addressing patient safety. *Anesthesiology*. 2002;97:1335-1337.
29. Corrigan JM, Eden J, Smith BM, eds. *Leadership by Example: Coordinating Government Roles in Improving Healthcare Quality Programs*. Washington, DC: Institute of Medicine; 2002.
30. Womer RB, Tracy E, Soo-Hoo W, Bickert B, DiTranto S, Barnsteiner JH. Multidisciplinary systems approach to chemotherapy safety: rebuilding processes and holding the gains. *J Clin Oncol*. 2002;20:4705-4712.
31. Schyve PM. Statement of the Joint Commission on Accreditation of Healthcare Organizations at the National Summit on Medical Errors and Patient Safety Research. September 11, 2000. Available at: http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/position+statements/summit+on+medical+errors.htm. Accessed December 23, 2002.
32. Bates DW, Leape LL, Cullen DJ, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA*. 1998;280:1311-1316.
33. Gandhi TK, Weingart SN, Seger AC, et al. Impact of basic computerized prescribing on outpatient medication errors and adverse drug events. *J Am Med Inform Assoc*. 2002;9(suppl 6):S48-S49.
34. Hunt DL, Haynes RB, Hanna SE, Smith K. Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systemic review. *JAMA*. 1998;280:1339-1346.
35. Bates DW, Spell N, Cullen DJ, et al. The cost of adverse drug events in hospitalized patients. *JAMA*. 1997;277:307-311.
36. Ortiz E, Meyer G, Burstin H. Clinical informatics and patient safety at the Agency for Healthcare Research and Quality. *J Am Med Inform Assoc*. 2002;9(suppl 6):S2-S7.
37. Dick DS, Steen EB, Detmer DE, eds. *The Computer-Based Patient Record: An Essential Technology for Health Care*. Rev ed. Washington, DC: Institute of Medicine; 1997.
38. Lovis C, Payne TH. Extending the VA CPRS electronic patient record order entry system using natural language processing techniques. *Proc AMIA Symp*. 2000:517-521.

©2003 American Medical Association. All rights reserved.